

REMARKS

The Office Action states that the Claims of the present application belong to 18 separate (independent and distinct) inventions, and requires a 18-way restriction. Applicants respectfully traverse. For examination purposes, applicants provisionally elect, with traverse, Group I which include Claims 1-4, 7-11, and 16-22.

As an initial matter, the Office Action states that alleged Groups VI to XVIII refer to the synthesis of aclacinomycin. However, this appears to be error because the present invention relates only to biosynthesis of nogalamycin.

Furthermore, this application is the national stage of a PCT application, and accordingly, the PCT unity of invention standard applies. The MPEP, following a court decision, see *Caterpillar Tractor Co. v. Commissioner of Patents and Trademarks*, 231 USPQ 590 (E.D. Va. 1986), mandates that

“when the [U.S. Patent and Trademark] Office considers international applications ... during the national stage as a Designated or Elected Office under 35 U.S.C. 371, PCT Rule 13.1 and 13.2 will be followed when considering unity of invention of claims of different categories without regard to the practice in national applications filed under 35 U.S.C. 111. ...

In applying PCT Rule 13.2 ... to national stage applications under 35 U.S.C. 371, examiners should consider for unity of invention all the claims to different categories of invention in the application and permit retention in the same application for searching ... claims to the categories which meet the requirements of PCT Rule 13.2.

MPEP § 1850 (underlining added).

The MPEP, further illustrated the three typical situations where unity of invention should be analyzed. See MPEP § 1850(B). One of the three situations is “Markush Practice.”

The situation involving the so-called Markush practice wherein a single claim defines alternatives (chemical or non-chemical) is also governed by PCT Rule 13.2. In this special situation, the requirement of a technical interrelationship and the same or corresponding special technical features as defined in PCT Rule 13.2, shall be considered to be met when the alternatives are of a similar nature.

When the Markush grouping is for alternatives of chemical compounds, they shall be regarded as being of a similar nature where the following criteria are fulfilled:

- (A) All alternatives have a common property or activity; and
- (B) (1) A common structure is present, i.e., a significant structural element is shared by all of the alternatives; or
- (C) (2) In cases where the common structure cannot be the unifying criteria, all alternatives belong to a recognized class of chemical compounds in the art to which the invention pertains.

...

In paragraph (C)(2), above, the words "recognized class of chemical compounds" mean that there is an expectation from the knowledge in the art that members of the class will behave in the same way in the context of the claimed invention. In other words, each member could be substituted one for the other, with the expectation that the same intended result would be achieved.

MPEP § 1850(B).

The instant application concerns the gene cluster involved in the biosynthesis of nogalamycin, an atypical anthracycline produced by *S. nogalater*, and the use of the cluster, or parts thereof (i.e. the genes included therein), to obtain new chemical compounds. The general inventive concept is that genes found in the cluster can be used in the biosynthesis of nogalamycin and in different combinations, i.e. as a larger DNA fragment or as single genes, in various host strains to create 'unnatural' chemical structures as exemplified in the application. It should also be noted that nogalamycinone has not been made before, neither by chemical synthesis nor by biosynthesis. This is because it is an intermediate of a complicated chemical structure, whose production is only possible by using the 'truncated biosynthetic pathway for nogalamycin' as described in the present application. It was a real surprise to be able to obtain nogalamycinone.

Applying the above "unity of invention" criteria to the present claims (specifically those related to the so-called Markush practice), it is apparent that all the polynucleotides in the claimed cluster share a common property, i.e., for the biosynthesis of nogalamycin, (satisfying the above criterion A); and all belong to a recognized class of chemical compound, i.e. polynucleic acid molecules (satisfying criterion B). Accordingly, all the claims should be examined together, and the restriction requirement should be withdrawn.

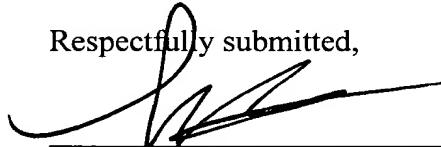
In view of the above, there should either be no extra burden to the Examiner to search all the claims, as the structures (sequences) of each of the genes are included in the sequence of the cluster.

If there are any questions regarding this response or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned.

If necessary to effect a timely response, this paper should be considered as a petition for an Extension of Time sufficient to effect a timely response, and please charge any deficiency in fees or credit any overpayments to Deposit Account No. 05-1323 (CAM #: 029381.49849US).

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Respectfully submitted,



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